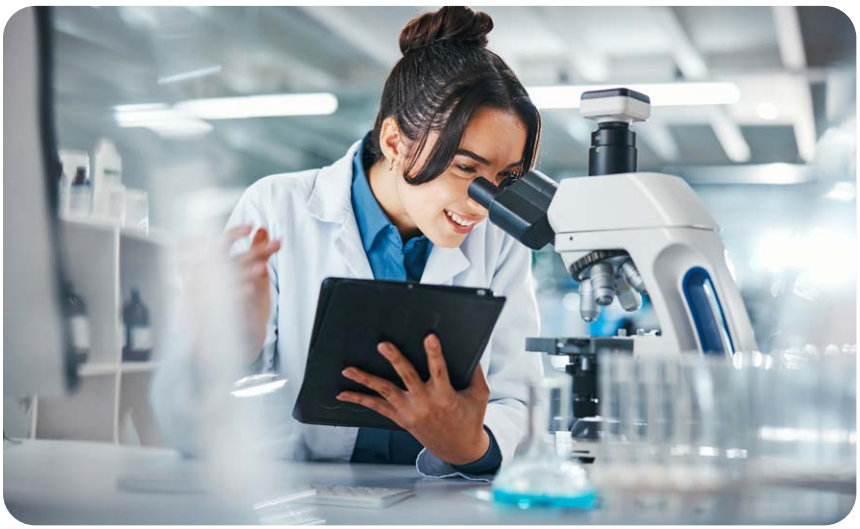
Product Stewardship & Access to Healthcare

Product Stewardship & Access to Healthcare

Product Quality & Access at the Core

Access to safe and effective medicines is crucial for universal healthcare coverage. We are committed to providing high-quality medications to patients and healthcare professionals worldwide.

With a dedicated team of over 2,900 skilled Research and Development (R&D) professionals and strategic R&D investments (comprising 6.2% of our FY25 sales), we prioritise the creation of specialty, branded generics, and generic medications across diverse therapeutic categories to enhance healthcare accessibility for our patients. Our robust distribution network, which includes distributors, stockists, and wholesalers, provides worldwide availability of medical products to patients in need.



Patient Safety

We carry out thorough evaluations and quality assurance measures to uphold product quality standards and adhere to all regulations. Swift detection and resolution of potential health and safety risks are crucial for maintaining product quality, protecting patient safety, and fostering trust with our stakeholders[32]. We consistently evaluate the risk-benefit profile of our products by following international quality and regulatory compliance standards and closely monitoring product safety[33].

Pharmacovigilance at Sun Pharma

Our Pharmacovigilance team takes a proactive stance on risk mitigation and product safety. Our system persistently tracks product safety and promptly responds to any adverse events[34]. The Product Safety Committee backs our Global Pharmacovigilance Policy, while the Independent Pharmacovigilance Quality Assurance team reports directly to the Chief Quality Officer.

Our pharmacovigilance team is dedicated to contingency planning and the mitigation and resolution of adverse events to improve quality control, workforce training, and patient safety. Utilising advanced IT solutions for efficient data processing, our pharmacovigilance team consists of approximately 100 skilled professionals, such as physicians and scientists. They manage Adverse Drug Reaction (ADR) cases, expedited reporting, risk management, safety signal management, and the consolidation of safety data into a centralised database for reporting to global regulatory authorities.

The Product Safety Committee supervises pharmacovigilance processes to ensure standards compliance, addresses safety issues, and establishes necessary remedial actions. Our Chief Quality Officer oversees an independent pharmacovigilance quality audit, based on a five-year strategy and annual plan. We also undergo regular inspections from regulatory bodies like the US Food and Drug Administration (US FDA), European Medicines Agency (EMA), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), Health Canada (HC), Japan's Pharmaceuticals & Medical Devices Agency (PMDA), and others to ensure compliance. Further details about specific US FDA inspections can be found in our FY25 Annual Report on page 289 via the link: SPIL-Annual-Report-2024-25.pdf

[32]GRI 3-3 | [33]GRI 416-1 | [34]GRI 416-2

Product Stewardship & Access to Healthcare

Product Quality

Our 'Quality Organisation Vision' is to globalise, harmonise and simplify GxP processes to ensure a sustainable quality culture. At Sun Pharma, we work towards continuous improvement of our Quality Management System, including all its elements and employ state-of-the-art electronic systems. We are building and maintaining a strong culture of quality through the ongoing development, training, and empowerment of our personnel.

We believe that producing safe and high quality products is everyone's responsibility.

We prioritise employee development, empowerment, and training to cultivate a culture that emphasises product quality. Through our 'Quality Vision,' we have developed a comprehensive quality management approach, aligning our global Quality Management System (QMS) with industry best practices and assurance processes.

Our quality standards encompass procurement, product distribution, stakeholder complaint management, investigations, and corrective and preventive actions. Our dedicated quality management team is committed to maintaining strict adherence to quality and safety standards. Our strategy emphasises sustainable quality design, data governance, process harmonisation, and the implementation of global quality metrics.

Quality Management System (QMS)

- Global QMS
- Cross-functional implementation of QMS including R&D, quality, and operations
- Adopting best practices, tools and procedures to ensure a comprehensive end-to-end product quality

Quality Practices

- Sustainable quality design
- Quality data governance
- Process harmonisation for enhanced compliance
- Global Quality metrics
- Sharing of internal and external learnings

Key QMS Elements

- **Procedural Documents:** Electronic document management systems - access control, printing control, and version control
- **Deviation and Investigation Analysis:** Periodic trend analysis
- **Training:** Instructor-led and electronic learning management systems, including a focused training course on Advanced Pharmacovigilance
- **Good Documentation Practices:** Implementation of good documentation practices in line with SOPs
- **Corrective and Preventive Actions (CAPA):** Robust CAPA management for all quality events, ensuring preliminary assessment, investigation, and effective corrective & preventive actions
- **Management Review Meeting:** Sun Pharma's senior management ensures the quality system governance through periodic quality reviews

Product Stewardship & Access to Healthcare

Quality Assurance Process

Compliance with GxP and country-specific regulations	Periodic inspections by regulatory agencies at manufacturing sites ensure compliance with cGMP certification requirements	Release of input and packaging material post qualification and testing
Ensuring product quality through in-process testing, finished goods testing, and stability testing	Stringent compliance is ensured with specifications relevant to each market/geographical requirement.	Prevention of recurring deviations, failures, and discrepancies by recording of investigation in the QMS
Comprehensive QMS system, including change management, deviation, and investigation management, CAPA, adverse events management, field alert reporting, complaint management, and recall process	Periodic audits are conducted by the Company's Corporate Quality team at all manufacturing facilities, contract manufacturing sites, and vendor locations	Training of employees involved in GxP activities through modules curated for job-specific roles

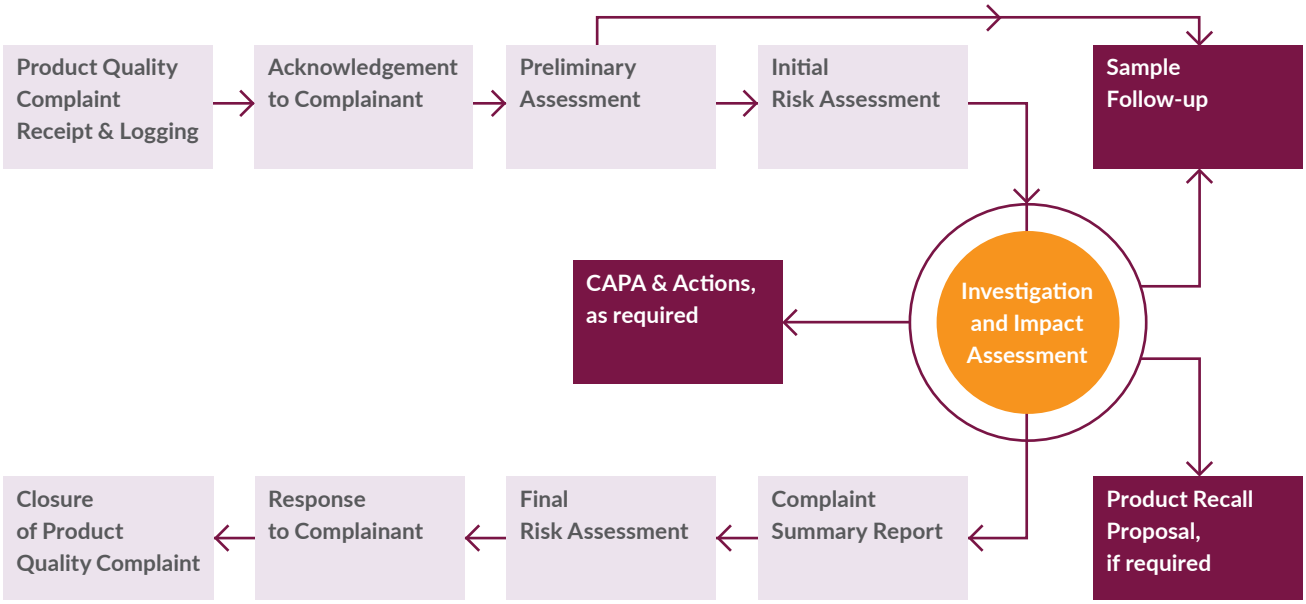
Product Quality Complaint and Recall Management Process

Sun Pharma's Global Standard Operation Procedure (GSOP) on Product Quality Complaint management entails a meticulous approach for addressing of product quality complaints. Upon receiving a complaint, it is documented in the system and undergoes an initial evaluation.

We conduct a preliminary assessment followed by an investigation. Based on the findings and root cause analysis, we implement Corrective and Preventive Actions (CAPA) to address the identified issues. A response is then provided to the complainant, ensuring clear communication and resolution of the issue.

Our GSOP on Product Recall Management provides requirements for managing product recalls and outlines the conditions that warrant such actions. The recall process involves a Global Recall Committee reviewing recommendations from the Site Recall Committee, processing the recall proposal, issuing recall notifications, closure of the recall and trend analysis. In FY25, we had no Class-I recalls and 20 Class-II recalls, with the total value of recalled products amounting to $ 1.46 million. During the reporting year, our manufacturing facilities underwent 50 regulatory inspections by agencies such as the USFDA, UK MHRA, EMA, PMDA, among others. The USFDA conducted two inspections at our manufacturing facilities, which resulted in four Form 483 observations.

Process of Redressal of Product Quality-related Complaints



Product Stewardship & Access to Healthcare

Responsible Product Stewardship

At Sun Pharma, we are dedicated to responsible product stewardship, maintaining the highest ethical standards throughout a product's lifecycle, from development and manufacturing to labelling and disposal.[35]

Ease of Access to Products

We strive to enhance the accessibility of our products across global markets, reaching both urban and rural areas. Our distribution network, including retailers, distributors, wholesalers, and carrying & forwarding agencies (CNFs)—ensures our products are available to patients worldwide.

Product Labelling and Information

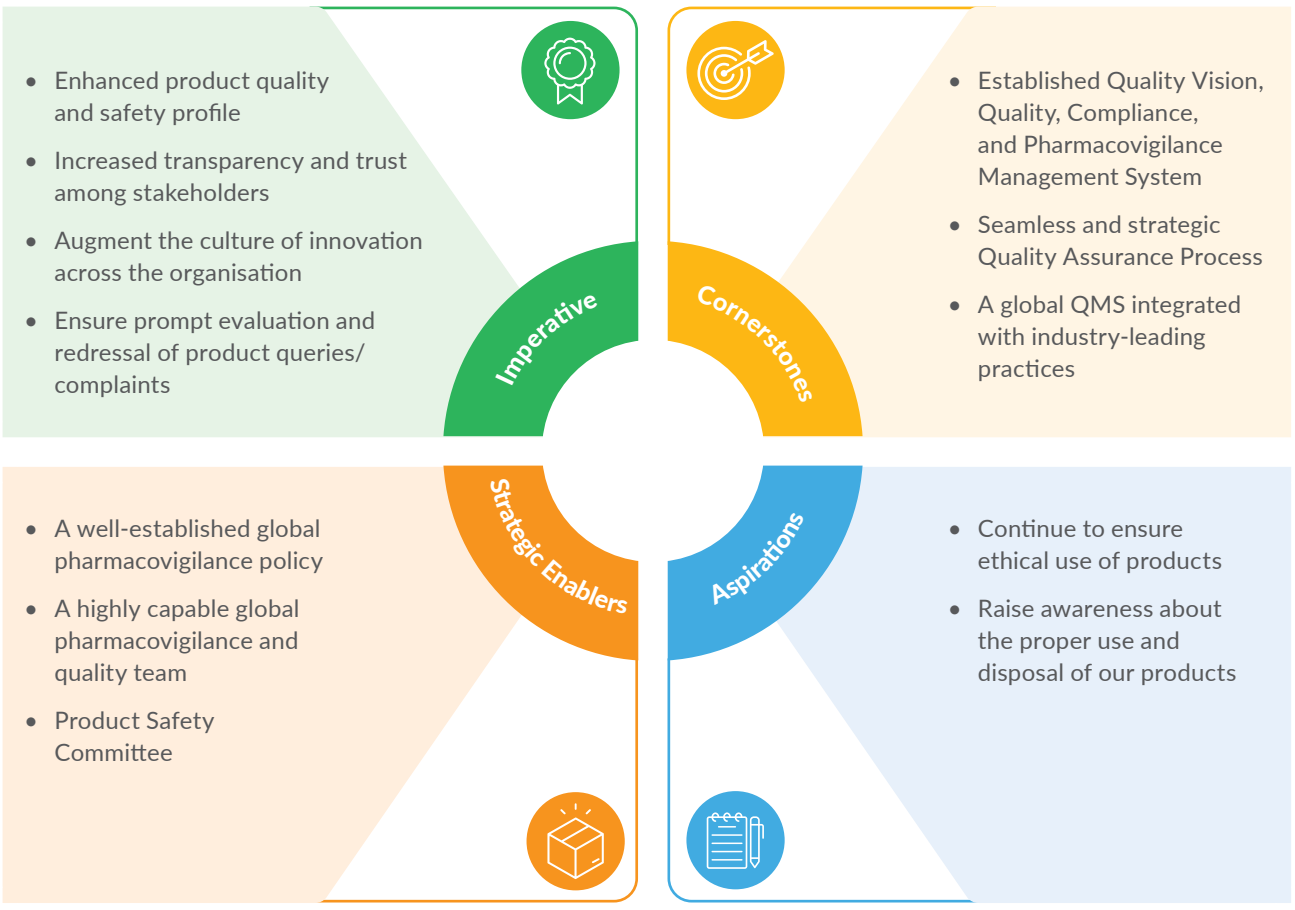
As part of our commitment to responsible product stewardship, we strictly comply with regulations concerning product labelling and information, including details on pharmacokinetics, safe usage, composition, clinical pharmacology, drug interactions, side effects, and storage requirements.[36]

In FY25, there were no incidents of noncompliance with various regulations that resulted in fines, penalties, warnings, or breaches of voluntary codes.[37]

Responsible Product Disposal

We adhere to local safety and environmental protocols for the proper disposal of returned or recalled products, ensuring that we meet all applicable laws and regional standards. Additionally, we meticulously document the quantities of disposed products and their corresponding destruction dates.

Foundational Pillars of Product Stewardship



[35]GRI 3-3 | [36]GRI 417-1 | [37]GRI 417-2 & 417-3

Product Stewardship & Access to Healthcare

Anti-counterfeit Measures

Awareness and Processes

We are dedicated to increasing awareness about the dangers of counterfeit medicines in impacted markets by implementing a robust anti-counterfeit governance management system. We have formed a specialised task force to address these threats and enhance safety. This task force ensures continuous monitoring of counterfeit medicines, utilising our track and trace technology and complaint management system to bolster safety and security measures.

Governance Mechanism

We ensure that our trademark and learning and development (L&D) teams deliver thorough training to our entire field force on identifying and reporting counterfeit medicines. Additionally, we have established a specialised task force consisting of experienced senior field personnel who receive targeted training to detect counterfeit medications. This task force is supported by a well-prepared field team that aids in the identification and reporting of such products. Our process is closely linked with key performance indicators (KPIs) to effectively measure and enhance the efficiency of our efforts.

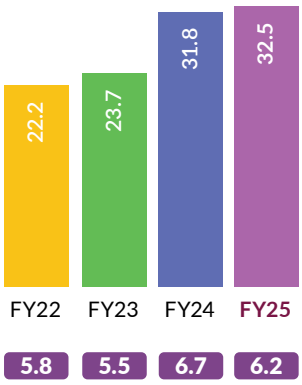
Management System

We have implemented a robust feedback mechanism to receive complaints from both complainants and marketing representatives, ensuring prompt reporting of issues and queries related to counterfeit products to the appropriate regulatory authorities. Our track and trace technology plays a crucial role in detecting and preventing the sale of counterfeit items. To further combat counterfeiting, we are enhancing our product packaging to make it easier for consumers to distinguish between genuine and fake medicines, continually working towards standardised and unique designs that reduce the risk of counterfeits. Additionally, a well-established complaint management system is in place to efficiently handle suspected cases of counterfeit products.

Innovation and Research & Development

Our expertise in Research and Development (R&D) underscores our commitment to creating innovative, safe, and effective products that address the global unmet medical needs of patients. Supported by a dedicated team of over 2,900 R&D professionals, along with our advanced chemistry and technological skills, we are able to develop a robust pipeline of specialty and complex generic products. Our R&D capabilities cover a broad range of dosage forms, including injectables, oral medications, liquids, ointments, gels, sprays, hormones, and oral products. Our R&D centres are regularly audited by various international regulatory authorities to ensure compliance with stringent quality and regulatory standards. Furthermore, we collaborate with academic institutions and industry experts to further enhance our R&D capabilities.

R&D Investments (in ₹ Billion)



Intellectual Property

Our intellectual property team is skilled in chemistry, analytical techniques, dosage forms, and global patent practices. As of March 31, 2025, our patent portfolio includes 3,229 filed patents and 2,459 granted patents, demonstrating our steadfast dedication to innovation and the integration of cutting-edge science.

FY25 R&D Highlights

₹32.5 Bn
Overall R&D investments

~280
Product dossiers developed and filed globally

1,300+
Molecules in our global portfolio across multiple geographies

Product Stewardship & Access to Healthcare

Our R&D Approach and Capabilities

Enablers

- Significant investments in R&D with a focus on developing specialty, complex generics, APIs, and process improvement.
- Dedicated R&D team of 2,900+ professionals with state-of-the-art R&D infrastructure.
- Compliant with global regulatory standards for maintaining high-quality.
- Aim to create new technologies such as using green reagents in API synthesis, applying Process Analytical Technology (PAT) tools, and executing advanced processing techniques.
- Comprehensive product life cycle management with backward integration for key products.
- Enhancing operational efficiency using Quality by Design (QbD) framework and Six Sigma methodologies.
- Development of innovative compact dosage forms with enhanced stability and decreased pharmacokinetic variability.
- Expansion of product portfolio to cater to the evolving needs of patients.

Capabilities

- Capability to develop various dosage such as orals, liquids, ointments, gels, sprays, and injectables.
- Biological capabilities, chemistry skills, and new drug development capabilities.
- Capability to develop non-infringing formulations and specialty/complex products.
- Broad product portfolio covering multiple therapeutic segments catering to diverse patient needs.
- Competencies to undertake clinical studies for specialty products and complex generics.

Ambitions

- Targeted investments to expand the specialty pipeline.
- Focus on developing complex generics.
- Growing focus on developing the R&D pipeline for Emerging Markets and India.
- Improved efforts in developing strategically important APIs.
- Collaborate with academia and industry experts to enhance our R&D capabilities.

Our Specialty R&D Pipeline (as of November 2025)

Product/ Molecule	Mechanism of Action	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Registration/ Approval
unloxcyt	anti-PD-LI	Metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced cSCC					
Nidlegy™	Immunocytokines	Melanoma & non-melanoma skin cancers					
Ilumya	IL-23 Antagonist	Psoriatic arthritis					
Fibromun	Innovative anti-cancer immunotherapy	Soft tissue sarcoma					
		Glioblastoma					
MM-II	Liposomal intra-articular lubrication	Pain in osteoarthritis					
GL0034	GLP-IR Agonist	Type 2 diabetes					

Note - All candidates for global markets except Nidlegy™ where Sun is commercial partner for Europe, Australia & New Zealand.
Nidlegy™ is a trademark of Philogen

Product Stewardship & Access to Healthcare

Reducing Environmental Impact through 'Green Chemistry'

The pharmaceutical industry is adopting a benign-by-design approach, employing non-toxic methods/tools/techniques/solvents for sustainable product development. Our R&D teams continuously innovate to minimise our products' ecological footprint through 'Green Chemistry' approaches.

Steps Taken to Reduce Environmental Impact

Leveraging Technology for Sustainable Operations

Our focus on innovation and technology empowers us to improve safety standards, increase therapeutic effectiveness, optimise workflows, advance technical capabilities, and ensure economic sustainability. To foster innovation and drive sustained business growth, a dedicated Centre of Excellence (CoE) has been established to support essential organisational functions such as R&D, quality assurance, finance, manufacturing, HR, and supply chain operations.

Decisions regarding technological integration are made collaboratively, considering proof of concept and business case approvals. Technology guidelines have been set to ensure effective project execution, aligning with global standards such as the Information Security Management System (ISMS) and the Information Technology Infrastructure Library (ITIL).

The Corporate Technology team has formulated an IT innovation and technology roadmap, while each department dedicates an annual budget to safeguard information security.

This budget factors in the current hardware landscape, ongoing initiatives, new projects, and external influences affecting information security.

Through targeted investments in advanced technologies, we've improved the availability of medicines around the world. There is a strong emphasis on strict compliance with global safety standards, alongside a continuous commitment to ensuring the quality of a diverse product portfolio.[38] In FY25, no information security or data privacy incidents were recorded.[39]

Our Approach to Information Security

At Sun Pharma, we have a robust monitoring system for information security in order to enhance data and information reliability and protection.

Continuous Awareness and Training

We enhance information security awareness through simulation-based learning for all employees.

24/7 Threat Monitoring

Our around-the-clock monitoring systems are designed to detect and address threats as part of our Managed Detect and Respond protocols.

Information Security Management System (ISMS)

We apply Information Security Management System (ISMS) protocols, Global Standard Operating Procedures (GSOPs), and Defence-in-depth strategies.

Transition to Zero-trust Security

We aim to advance towards a zero-trust-based security infrastructure, enhancing our security posture with comprehensive training and controls.

Standard Operating Procedures (SOPs)

We implement Standard Operating Procedures (SOPs) globally for consistent data management across all locations.

Adherence to Industry Standards

We follow best practices aligned with the National Institute of Standards and Technology (NIST) and ISO 27001:2013 to effectively manage information security risks.

[38]GRI 3-3 | [39]GRI 418-1

Innovation and Technology

Information Security Governance

At Sun Pharma, we uphold a strong governance structure to manage information security concerns, risks, and resilience. Our Risk Management Committee at the Board level supervises the governance processes and practices related to information security. We also have designated a Chief Information Security Officer (CISO) who holds direct responsibility for overseeing all cybersecurity matters throughout our operations.

Information Security Policy

Our Information Security Policy offers guidance and support to ensure the implementation and upkeep of standards for safeguarding our information systems. Through this Policy, we

- Consistently advance information security systems
- Ensure data integrity and protection
- Oversee and address information security threats
- Define personal accountability for information security across the entire workforce

Our Compliance with Global Data Integrity and Security Standards:

Compliance with USFDA data integrity and cGMP standards

Complying with Information Security Management System standards using ISO 27001 as a guidance

Following PDA Report 80 for creating a data integrity management system in our laboratories

Adhering to data protection regulations to safeguard personal data at operational locations

Our Focus on Data Integrity and Security

Policy Enforcement and Training

We enforce stringent policies and processes, bolstered by information security awareness training, to uphold data security and integrity throughout the organisation.

Data Integrity and Security Segmentation

We tackle data integrity and security challenges by categorising them into three primary areas: cyber-attacks, insider threats, and manufacturing process integrity.

Comprehensive Defence Strategies

We employ a variety of strategies to mitigate cyber-attack risks, including a 24/7 Security Operations Centre (SOC), threat intelligence governance services, and collaboration with security experts.

Incident Management Alignment

We align our Incident Management Policy with ISO 27001 standards to ensure our response protocols are effective.

Coordinated Investigations

We deploy data leakage prevention tools to mitigate insider threats, conducting further investigations in collaboration with business and HR functions.

Standard Operating Procedures (SOPs) Implementation

We implement globally benchmarked Standard Operating Procedures (SOPs) for manufacturing operations, emphasising root cause analysis and information security risk assessment.

Sustainable Supply Chain

Sustainable Supply Chain

Focus on Responsible Supply Chain

Recognising that product accessibility underpins sustainable value creation, we have implemented a comprehensive supply chain management framework. This system seamlessly combines logistics, procurement, production planning, and inventory control to ensure operational excellence and reliability throughout the organisation. Our supply chain management system works diligently to ensure that we manufacture and supply products in line with market demand.[40]

To ensure efficiency and effectiveness, our procurement and supply chain policies, systems, and processes are regularly reviewed under the guidance of senior management. These evaluations aim to align our operations with industry best practices and strategic objectives, enabling the identification of areas for improvement and enhancement of overall processes. Our cross-functional approach to supply chain management reflects our commitment to sustainability and patient well-being. By optimising resource utilisation, reducing waste, and streamlining operations, we ensure the timely and reliable delivery of medicines. In FY25, our supply chain remained stable with no significant changes or modifications.

Supply Chain Approach – Foundational Pillars

Procurement

Our procurement team plays a critical role in maintaining an uninterrupted supply of raw materials, as well as primary and secondary packaging components and finished formulations. This proactive approach supports the consistent development and production of APIs and formulations, ensuring their availability in key markets and contributing to our broader sustainability and healthcare access goals.

Planning and Inventory Management

Our integrated management system leverages Distribution Requirement Planning (DRP), Market Requirement Planning (MRP), and other advanced planning tools to accurately assess inventory needs and efficiently manage supply chain operations. This data-driven approach enhances responsiveness, reduces waste, and supports sustainable delivery of products to the markets we serve.

Distribution, Logistics & Finished Goods Delivery

Our distribution and logistics team works in close coordination with the supply chain function to ensure the timely and efficient delivery of finished goods and services. This collaborative approach strengthens our ability to meet market demands reliably, supporting our commitment to operational excellence and patient access.

An Overview of Our Supply Chain Operations[41]

Upstream

The supply planning team conducts demand and sales projections and engages in capacity planning for production across short-, medium-, and long-term periods.

Supply planning teams collaborate and coordinate with the manufacturing, procurement, and operations departments to maintain supply chain integrity.

Downstream

The sales, marketing team and demand planning teams collaborate to analyse market trends and scenarios to forecast demand.

The supply planning and procurement team works with manufacturing sites and suppliers to ensure the availability of inventory in line with the requisite norms. The team also ensures finished product are in line with product demand, in response to the sales forecasts.

[40]GRI 3-3 | [41]GRI 2-6

Sustainable Supply Chain

Effective Supply Chain Monitoring

At Sun Pharma, we have implemented a comprehensive monitoring framework within our supply chain operations to proactively identify, assess, and mitigate potential risks. Guided by structured principles and detailed checklists, this systematic approach enables us to evaluate vulnerabilities and develop targeted strategies to address emerging challenges. This reinforces our commitment to resilient, sustainable, and secure supply chain practices.

We conduct regular evaluations of our vendors as part of this monitoring process, ensuring all critical suppliers undergo Critical Quality Attributes (CQA) audits every three years. We screen our vendors to evaluate their compliance with a broad range of ESG indicators, which include legal compliance, safety standards, respect for human rights, labour practices, working conditions, and environmental sustainability.

To reinforce our commitment to ESG principles across our business operations, we have established a Supplier & Third-Party Code of Conduct, expecting all third-party vendors, suppliers, and business partners to adhere to the principles outlined in this code.

Initiatives

- Conduct systematic reviews of suppliers in accordance with established guidelines.
- Source essential materials from a diverse range of suppliers.
- Periodically review compliance management practices and contract performance.
- Assess new suppliers through regular audits, ensuring alignment with the CQA policy, Supplier & Third-Party Code of Conduct, internal quality standards, ESG parameters, and relevant regulations.
- The Strategic Procurement Committee identifies and prioritises significant risks and implements mitigation strategies.
- Conduct ESG-focused capacity-building for internal stakeholders.

Local Sourcing

We strive to source locally whenever possible to support and strengthen local businesses. For Sun Pharmaceutical Industries Limited (SPIL) as a standalone entity, local suppliers represented 73% of our procurement.[42]

Utilising local sourcing reduces currency risk by decreasing reliance on imports and encourages collaboration. It aids in the expansion of regional industries and economies, and partnering with local vendors helps generate job opportunities. Moreover, a key advantage of local sourcing is its positive environmental impact; shorter transportation routes lead to reduced carbon emissions from long-haul transport, thereby lowering our environmental footprint.

[42]GRI 204-1